

## **DETAILED ACTION**

### **STATUS OF CLAIMS**

1. This office action is responsive to the amendment filed on 10/22/2010. As directed by the amendment: claims 26, 27, 30 and 42 have been amended, claims 1, 4-9, 12, 15-25, 43 and 44 have been cancelled, claims 3, 33-37 and 41 have been withdrawn and new claims 51-54 have been added. Thus, claims 2, 10, 11, 13, 14, 26-32, 38-40, 42 and 45-54 are presently pending in this application.

### **EXAMINER'S AMENDMENT**

2. An examiner's amendment to the record appears below.
3. Claims 10, 42 and 51-54 are now cancelled.
4. Current claim 11 is replaced by the following claim:

The method of claim 10, wherein the reinforced peripheral region has a thickness greater than a central portion of said first piece of flexible material.

5. Current claim 26 has been replaced by the following claim:

6. A method for modifying blood flow in a vascular vessel, the method comprising:  
percutaneously delivering an implant to a site within a vascular vessel, the implant including one or more pieces of flexible material, said one or more pieces of flexible material including a first piece of flexible material which includes a reinforced peripheral region extending along an outer edge of said first piece of flexible material, said reinforced peripheral region configured to extend longitudinally along and at least

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partially circumferentially around a wall of the vascular vessel upon implantation and having extending therefrom an array of vessel wall-penetrating elements that is more than two vessel wall-penetrating elements wide and said array includes vessel wall-penetrating elements arranged longitudinally and generally laterally with respect to one another; and

percutaneously deploying the implant in the vascular vessel so as to form a structure that selectively permits blood flow in a first direction and resists blood flow in a second direction, said percutaneously deploying including driving vessel wall-penetrating elements of said first array into a wall of the vascular vessel so as to secure said reinforced peripheral region to said vascular vessel wall with said reinforced peripheral region extending longitudinally along and at least partially circumferentially around the vascular vessel wall.

7. Claim 26 is allowable. The restriction requirement between species and subspecies, as set forth in the Office action mailed on 10/01/2009, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claims 3, 33-37 and 41, are no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim. In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory

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and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

8. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

9. Authorization for this examiner's amendment was given in a telephone interview with Timothy Paul on 11/18/2010.

### **REASONS FOR ALLOWANCE**

10. Claims 2, 3, 11, 13, 14, 26-41 and 45-50 are allowed.

The following is an examiner's statement of reasons for allowance: claims in this application are allowable due to the amended limitation "said one or more pieces of flexible material including a first piece of flexible material which includes a reinforced peripheral region extending along an outer edge of said first piece of flexible material... and having extending therefrom an array of vessel wall-penetrating elements that is more than two vessel wall-penetrating elements wide" as set forth in claim 26. A vascular valve prosthesis having flexible leaflet material and an reinforced edge with an array of barbs that is more than two barbs wide, has not been found anticipated by or obvious over prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YASHITA SHARMA whose telephone number is (571)270-5417. The examiner can normally be reached on Monday - Thursday, 8 am to 4 pm EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Y. S./  
Examiner, Art Unit 3774

/Alvin J Stewart/  
Primary Examiner, Art Unit 3774